DEPARTMENT OF HEALTH & HUMAN SERVICES

94673d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 15, 2004 W/L 34-04

Mr. Bernardo T. Chua
President
Gano Excel U.S.A. Inc.
4981 Irwindale Ave., Suite 800
Irwindale, CA 92260

Re: promotion of various products including Ganoderma capsules, Excellium capsules, Gano Garcinia capsules, and Sakanno

Dear Mr. Chua:

This letter is in reference to the products marketed and distributed by your firm Gano Excel U.S.A. that contain the ingredient "Ganoderma." The various products are: Ganoderma capsules, Excellium capsules, Gano Garcinia capsules, and Sakanno.

On November 5-19, 2003, representatives of the Food and Drug Administration (FDA) inspected your firm and collected labeling for your products. We also reviewed your website at www.ganoexcel.com. Our review of your website and the labeling of your products indicates serious violations of the Federal Food, Drug and Cosmetic Act (the Act). We have determined that your products are drugs under Section 201(g)(1)(B) of the Act because they are intended to treat, mitigate, cure, diagnose, or prevent disease. You can find the Act and FDA regulations regulations on the Internet through links on FDA's web page www.fda.gov.

Your web site at the address: http:// www.ganoexcel.com contains the following claims about treatment, prevention, and diagnosis of disease:

- *"Ganoderma helps to detect hidden diseases..."*
- Ganoderma, *"is known ... for its power to remove...excess cholesterol...."*
- Under "Why we need to take Ganoderma?" it states that Ganoderma *"has the ability... to discover if we have hidden diseases in the body. Then it removes the*

toxins and enables the body to treat a wide spectrum of diseases with the natural immune system."

- The "Testimony" section of your website promotes Gano Excel for the treatment of gout, diabetes, and psoriasis.

These drugs are misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use.

The labeling of your products indicates that you intend to sell Ganoderma capsules, Excellium capsules, and Sakanno as dietary supplements. If you intend to market these products as dietary supplements, they must meet the definition of dietary supplements in Section 201(ff) of the Act, and must comply with the applicable food labeling regulations in Title 21 of the Code of Federal Regulations, Part 101 (21 CFR 101). Even if the products meet the legal definition of dietary supplements, however, they may be subject to regulation as drugs based on claims in labeling or advertising. Section 403(r)(6) of the Act provides that structure/function claims may be made on the labeling for dietary supplements under certain circumstances. Marketing a dietary supplement with express or implied claims to prevent, treat, mitigate, cure, or diagnose a specific disease, or class of diseases, violates the Act unless FDA has authorized the claim in accordance with applicable health claim regulations, see 21 CFR 101.14 and 101.70, through the new drug approval process, see 21 CFR 314, or through the issuance of an OTC monograph, see 21 CFR 330.

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. Please notify this office in writing, within fifteen (15) days from the receipt of this letter, as to the specific steps you have taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the corrections will be implemented.

Your written reply should be addressed to Compliance Officer MaryLynn Datoc at the above address.

Sincerely,

Alonza E. Cruse
District Director